REMARKS

1. Withdrawn Objections and Rejections

Applicant notes with appreciation the withdrawal of the previous objections to the drawings, specification, title, and Claims 2, 3, and 5-21 and the rejection of Claims 8-11 under 35 USC 112, second paragraph.

2. Specification Objection

The Specification has been objected to because the hard copy of the sequence listing that was submitted on 18 April 2011 apparently does not match the computer readable copy (CRF) that was submitted on 30 January 2008. Applicant currently is investigating this. Additionally, if and when any discrepancy is found, Applicant intends to have an expert company prepare the sequence listing and CRF. To avoid the expense of such a project, Applicant requests the stay of requiring the sequence listing and CRF until the Examiner indicates there is allowable subject matter in the claims.

3. Claim Amendments

Claims 1-30 have been canceled without prejudice in this response or in a previous response.

Claim 31 has been amended to incorporate the subject matter of Claim 32 and to even more clearly define the matter for which protection is sought. The wording of the claim now recites a specific embodiment of the pharmaceutical product specific for the vaccination of vertebrates. No new matter has been added.

Claim 32 has been canceled without prejudice and its subject matter incorporated into Claim 31. No new matter has been added.

Clam 33 has been amended to depend from Claim 31 as intended rather than from Claim 1. No new matter has been added.

New Clam 34 provides for the dosage of pollen in the pharmaceutical product in micrograms per gram of body weight. Support for this claim can be found in Examples 3-12 of the Specification in which 5µg to 50µg of the pollen grains were included in the pharmaceutical product and were dosed to laboratory rats, which weigh between 250g and 350g. No new matter has been added.

New Claim 35 is analogous to Claim 31, but using the language presented in Claims 28 and 29. No new matter has been added. In the examples recited in the application, only part of the promoter region was used and was sufficient to control the expression of the downstream coding sequence. Accordingly, for the purposes of new Claim 35, the specification of this promoter fragment is clearly described and is consistent with the application as filed. For instance, FIG. 6 illustrates the gene construction ProAtGRP17. This sequence is 2421 bp long, and comprises the whole coding sequence of the AtGRP17 gene (solid arrow at right, ending at the Nco I restriction site) and part of the AtGRP17 promoter region (empty arrow at left, starting at Xba I restriction site). This fragment of the AtGRP17 promoter region is 616 bp long, as indicated in the description of FIG. 7. Accordingly, the promoter region corresponds to the last 616bp of the AtGRP17 promoter region. This specific construction provides the expression of the desired gene product, but also this expression is strictly time and tissue localized. In other words, no expression of the coded gene product was found in any other tissue or cell of the plant, as shown in FIG. 9 and its description. Accordingly, this specific construction provides advantages over other similar ones and/or constitutes an alternative that is not recited in the prior art.

New Clam 36 is identical to Clam 33 but dependent from Claim 34. No new matter has been added.

New Clam 37 provides for the dosage of pollen in the pharmaceutical product in micrograms per gram of body weight. Support for this claim can be found in Examples

3-12 of the Specification in which 5µg to 50µg of the pollen grains were included in the pharmaceutical product and were dosed to laboratory rats, which weigh between 250g and 350g. No new matter has been added.

4. Claim Objections

Claim 31 is objected to for language informalities. Applicant has addressed the informalities in the amendments to the claims herein. No new matter has been added. Applicant requests the withdrawal of these grounds for rejection of Claim 31.

5. 35 USC 112, Second Paragraph, Rejections

Claims 31-33 have been rejected under 35 USC 112, second paragraph, regarding the use of the term AtGRP17.

Applicant has amended Claim 31 to attempt to address the Examiner's concern. Applicant requests the withdrawal of this ground for rejection of Claims 31-33.

New Claim 34 is phrased in the terms of SEQ numbers.

6. 35 USC 102(b) Rejections

Claims 1-3 and 5-21 have been rejected under 35 USC 102(b) by WO 99/49063 (Robert '063). Claims 31-33 have been rejected under 35 USC 102(b) by US 2003/0182691 to Robert (Robert '691).

To simplify and speed up the examination, Claims 1-30 have been canceled and Applicant is proceeding on Claims 31 and 33-37. As Claims 1-3 and 5-21 have been canceled, Applicant requests the withdrawal of the rejection of these claims based on Roberts '063.

Roberts '691 is clearly directed to other purposes, and its content, purposes and mainly the actual tests performed are completely different. For example, Paragraph 0014 of Roberts '691 states that "the approach described herein is primarily directed at modifying pollen, and in some instances affects the interaction between pollen and stigma". Further, on Paragraph 0136 of Roberts '691, the meaning of "pollen function" is clearly stated, which is for its biological roles as plant gamete. Therefore, Roberts '691 is not primarily intended to provide the specific "use" of pollen grain, or, more precisely, the "pharmaceutical product" of the present invention that was actually developed and tested, and that provided the unexpected results.

Although Paragraphs 0015 and 0075 of Roberts '691 briefly recite that modified pollen grains could be used for "alleviating allergenic responses", no single test or proof-of-concept was provided in this regard. Also, as one of ordinary skill in the immunology field knows: (i) modulating allergic responses is quite different from providing vaccination responses and in most instances these are considered opposite mechanisms; and (ii) approaches for vaccination and allergy treatment are generally quite different, and only actual tests can support a trustful claim for the use of an actual product, which was not given in Roberts '691. Thus, even if such examples or tests were given in Roberts '691 (and none were), they would not anticipate the claims of the present invention because neither the AtGRP17 gene nor the AtGRP17 promoter region is disclosed or fairly taught cited in Roberts '691. Further, the specific use of part of said promoter region is an additional and advantageous selection, for the highly specific temporal and spatial expression pattern with the use of a much smaller promoter region, providing easier cloning/transformation.

Anticipation under 35 USC 102(b) requires "the disclosure in a prior art reference each and every element of the claimed invention." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986); *see also verdegall Bros. V. Union Oil Co. of California,* 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("a claim is anticipated only if each and every element as set forth in the claim is found, either

expressly or inherently described, in a single prior art reference"). The absence of one element from the cited prior reference negates anticipation. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ2d 409 (Fed Cir. 1984). AS discussed above, Roberts ,691 does not disclose or fairly teach each and every element of Claim 31 or new Claim 34.

Thus, in Roberts '691, the disclosed promoters and/or their coding regions are multiple, but all are different from those of the present invention (AtGRP17). Additionally, the AtGRP17 gene product (which is used in translational fusion in the product of the present invention) has 49 kDa and ***is the most abundant protein of the pollen grain surface***, corresponding to 21% of the total protein content of the surface pollen grain (see, e.g., Mayfield & Preuss, 2000). The AtGR17 gene product also is known to enhance the stability of pollen grains and to interfere with its hydration process. This, too, is distinct from Roberts '691.

Accordingly, the use of the strategy of the present invention at best can be deemed as an alternative to that disclosed in Roberts '691. The present invention is different and clearly provides benefits over Roberts '691. The substantial test results provided in the present Specification are robust proof of concept of the use of whole pollen grains under several regimes for obtaining a consistent, statistically significant, and highly unexpected protection-like response (instead of the expected allergic type response), as revealed by the cellular and molecular responses detected and disclosed in the application as filed.

As such, Applicant submits that Claims 31 and 33-37 are not anticipated by Robert '691, and requests that the Examiner withdraw these grounds for rejection.

CONCLUSION

Applicant submits that the application and claims are in condition for allowance and respectfully requests such action.

Respectfully submitted,
SMITH RISLEY TEMPEL SANTOS LLC

/lpcolton/

Laurence P. Colton
USPTO Reg. No. 33,371

SMITH RISLEY TEMPEL SANTOS LLC
Two Ravinia Drive, Suite 700
Atlanta GA 30346

Tel: 770.709.0023
Fax: 770.804.0900
E-Mail: lcolton@srtslaw.com